education of providers and stakeholders with respect to health care reform and certain provisions of the HITECH Act enacted as part of the ARRA.

The charter will terminate on January 19, 2023, unless renewed by appropriate action. The APOE was chartered under 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended. The APOE is governed by provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

In accordance with the renewed charter, the APOE will advise the Secretary and the CMS Administrator concerning optimal strategies for the following:

- Developing and implementing education and outreach programs for individuals enrolled in, or eligible for, Medicare, Medicaid, the CHIP, and coverage available through the Health Insurance Marketplace® and other CMS programs.
- Enhancing the federal government's effectiveness in informing Medicare, Medicaid, CHIP, or the Health Insurance Marketplace® consumers, issuers, providers, and stakeholders, pursuant to education and outreach programs of issues regarding these programs, including the appropriate use of public-private partnerships to leverage the resources of the private sector in educating beneficiaries, providers, partners and stakeholders.
- Expanding outreach to minority and underserved communities, including racial and ethnic minorities, in the context of Medicare, Medicaid, CHIP, and the Health Insurance Marketplace® education programs and other CMS programs as designated.
- Assembling and sharing an information base of ''best practices'' for helping consumers evaluate health coverage options.
- Building and leveraging existing community infrastructures for information, counseling, and assistance.
- Drawing the program link between outreach and education, promoting consumer understanding of health care coverage choices, and facilitating consumer selection/enrollment, which in turn support the overarching goal of improved access to quality care, including prevention services, envisioned under the Affordable Care Act.

The current members of the Panel as of April 7, 2022, are as follows:

- Julie Carter, Senior Federal Policy Associate, Medicare Rights Center.
- Scott Ferguson, Psychotherapist, Scott Ferguson Psychotherapy.
- Jean-Venable Robertson Goode, Professor, Department of Pharmacotherapy and Outcomes Science, School of Pharmacy, Virginia Commonwealth University.
- Ted Henson, Director of Health Center Performance and Innovation, National Association of Community Health Centers.
- Joan Ilardo, Director of Research Initiatives, Michigan State University, College of Human Medicine.
- Daisy Kim, Policy Manager, Asian & Pacific Islander American Health Forum.
- Cheri Lattimer, Executive Director, National Transitions of Care Coalition.
- Cori McMahon, Vice President, Tridiuum.
- Alan Meade, Director of Rehabilitation Services, Holston Medical Group.
- Neil Meltzer, President and CEO, LifeBridge Health.
- Michael Minor, National Director, H.O.P.E. HHS Partnership, National Baptist Convention USA, Incorporated.
- Jina Ragland, Associate State Director of Advocacy and Outreach, AARP Nebraska.
- Morgan Reed, Executive Director, Association for Competitive Technology.
- Margot Savoy, Senior Vice President, American Academy of Family Physicians.
- Congresswoman Allyson Schwartz, Senior Advisor, FTI Consulting.
- Matthew Snider, JD, Senior Policy Analyst, Unidos US.
- Tia Whitaker, Statewide Director, Outreach and Enrollment, Pennsylvania Association of Community Health Centers.

II. Provisions of This Notice

In accordance with section 10(a) of the FACA, this notice announces a meeting of the APOE. The agenda for the June 23, 2022 meeting will include the following:

- Welcome and listening session with CMS leadership
- Recap of the previous (April 7, 2022) meeting
- CMS programs, initiatives, and priorities
- An opportunity for public comment
- Meeting summary, review of recommendations, and next steps

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should submit a written copy of the oral presentation to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice. The number of oral presentations may be limited by the time available. Individuals not wishing to make an oral presentation may submit written comments to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

III. Meeting Participation

The meeting is open to the public, but attendance is limited to registered participants. Persons wishing to attend this meeting must register at the website *https://www.eventbrite.com/e/apoe-june-23-2022-virtual-meeting-tickets-323499494697* or contact the DFO at the address or number listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice. This meeting will be held virtually. Individuals who are not registered in advance will be unable to attend the meeting.

IV. Collection of Information

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: June 1, 2022.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2022–12136 Filed 6–3–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–3787]

Electromagnetic Compatibility of Medical Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is

announcing the availability of a final guidance entitled ''Electromagnetic Compatibility (EMC) of Medical Devices.'' FDA has developed this guidance document to recommend information that should be provided in a premarket submission (*i.e.,* premarket approval application (PMA), humanitarian device exemption (HDE), premarket notification (510(k)) submission, investigational device exemption (IDE), De Novo request, and certain biologics license applications (BLAs) and investigational new drug (IND) applications to demonstrate electromagnetic compatibility (EMC) for electrically powered medical devices and medical devices with electrical or electronic functions. This guidance provides specific technical information to address the recommendations originally described in the guidance entitled ''Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices,'' which was published July 11, 2016 (2016 EMC guidance).

DATES: The announcement of the guidance is published in the **Federal Register** on June 6, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- *For written/paper comments submitted to the Dockets Management Staff,* FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–3787 for ''Electromagnetic Compatibility (EMC) of Medical Devices.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Electromagnetic Compatibility (EMC) of Medical Devices'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Seth J. Seidman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 1108, Silver Spring, MD 20993–0002, 301–796–2477; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed this guidance document to recommend information that should be provided in a premarket submission (*i.e.,* PMA, HDE, 510(k), IDE, De Novo request, and certain BLAs and IND applications) to demonstrate EMC for electrically powered medical devices and medical devices with electrical or electronic functions. Typically, the review of EMC information in a submission is based on the risk associated with malfunction or degradation of the medical device under consideration, where malfunction or degradation could be caused by inadequate EMC. The review is also based on the use of appropriate consensus standards. This guidance, when final, will replace the FDA guidance entitled ''Information to Support a Claim of Electromagnetic

Compatibility (EMC) of Electrically-Powered Medical Devices'' (2016 EMC guidance), which was published July 11, 2016. This guidance provides additional technical information to address the recommendations in the 2016 EMC guidance.

FDA recognizes and anticipates that the Agency and industry may need up to 1 year to perform activities to operationalize the policies within the guidance, *only* for in vitro diagnostic products. Because this guidance generally reflects current practice for the assessment of EMC for other device types, but some activities to fully operationalize the policies are needed (*e.g.,* updates to eSTAR [1]), FDA intends to implement this guidance 60 days after issuance for device types within the scope of this guidance, excluding in vitro diagnostic products. If new information regarding electromagnetic compatibility as outlined in this guidance is not included in a premarket submission for an in vitro diagnostic received by FDA before or up to 1 year after the publication of this guidance or for other device types within the scope of this guidance before or up to 60 days after the publication of this guidance, FDA does not generally intend to request such information during the review of the submission. FDA does, however, intend to review any such information if submitted.

A notice of availability of the draft guidance appeared in the **Federal Register** of November 17, 2020 (85 FR 73276). FDA considered comments received and revised the guidance as appropriate in response to the comments, including clarification of scope; addressing the use of IEC 60601–1–2:2020, which was published after the draft guidance was issued; and adding a transition period to facilitate the implementation of the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on EMC of medical devices. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products* or from the Center for Biologics Evaluation and Research at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.* This guidance document is also available at *https://www.regulations.gov* and *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Electromagnetic Compatibility (EMC) of Medical Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400057 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB Control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
803	Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting.	0910–0437
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910–0073

Dated: May 31, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–12099 Filed 6–3–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities.

Date: June 28–29, 2022.

Time: 9:00 a.m. to 8:00 p.m.

[1] Available at *https://www.fda.gov/medical-devices/premarket-notification-510k/voluntary-estar-program.*